Press release, November 13, 2023

Medivir to present clinical data at ASCO-GI with fostrox + Lenvima in HCC and shares positive response from Type D meeting with FDA

Stockholm — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments for cancer in areas of high unmet medical need, announced today that clinical data from the ongoing phase 1b/2a study of in fostroxacitabine bralpamide (fostrox) in combination with Lenvima® (lenvatinib) in hepatocellular carcinoma (HCC), will be presented at the ASCO Gastrointestinal Cancers Symposium, January 18-20, 2024 in San Francisco, USA.

The abstract, titled *"First safety and efficacy data from phase Ib/IIa study of fostroxacitabine bralpamide (fostrox, MIV-818) in combination with lenvatinib in patients with hepatocellular carcinoma (HCC)*" will be presented by Dr. Maria Reig, Director of the Barcelona Clinic Liver Cancer (BCLC) and the Liver Oncology Unit at the Hospital Clinic of Barcelona in Spain. The presentation will include updated safety and independently reviewed efficacy data regarding the clinical benefit of fostrox in combination with Lenvima, a tyrosine kinase inhibitor.

Medivir furthermore announces that interactions with the FDA regarding fostrox's clinical development plan have intensified with a first Type D meeting with a positive response regarding critical elements of the design for the planned phase 2b study. The finalization of the study design will take place in connection with an upcoming Type C meeting to enable study start in 2024. The goal of the upcoming study, as previously communicated, is to apply for accelerated approval.

- "In this phase 1b/2a study, the fostrox + Lenvima combination has shown a good safety profile and promising tumor control in second-line HCC, and we confidently look forward to presenting these data at ASCO-GI. Despite some success with first-line immunotherapy, patients with HCC have a poor prognosis and effective second-line treatment options are lacking. The data from this study, combined with the great medical need, opens the possibility of an accelerated approval path, which is why we are now planning for a pivotal, randomized phase 2b study. The FDA's response at our Type D meeting was a positive step towards our ambition to give this vulnerable patient group access to fostrox as a new treatment option.", says Pia Baumann, CMO at Medivir.

The abstract and the poster will be available on Medivir's website after the presentation.

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About fostrox

Fostrox is a type of smart chemotherapy that delivers the cell-killing compound selectively to the tumor while minimizing the harmful effect on normal cells. This is achieved by coupling an active chemotherapy (troxacitabine) with a prodrug tail. The prodrug design enables fostrox to be administered orally and travel directly to the liver where the active substance is released locally in the liver. With this unique mechanism, fostrox has the potential to become the first liver-targeted, orally administered drug that can help patients with various types of liver cancer. A phase 1b monotherapy study with fostrox has been completed and a phase 1b/2a combination study in HCC is ongoing.

About primary liver cancer

Primary liver cancer is the third leading cause of cancer-related deaths worldwide and hepatocellular carcinoma (HCC) is the most common cancer that arises in the liver. Although existing therapies for advanced HCC can extend the lives of patients, treatment benefits are insufficient and death rates remain high. There are approximately 660,000 patients diagnosed with primary liver cancer per year globally and current five-year survival is less than 20 percent[1)]. HCC is a heterogeneous disease with diverse etiologies, and lacks defining mutations observed in many other cancers. This has contributed to the lack of success of molecularly targeted agents in HCC. The limited overall benefit, taken together with the poor overall prognosis for patients with intermediate and advanced HCC, results in a large unmet medical need.

About Medivir

Medivir develops innovative drugs with a focus on cancer where the unmet medical needs are high. The drug candidates are directed toward indication areas where available therapies are limited or missing and there are great opportunities to offer significant improvements to patients. Medivir is focusing on the development of fostroxacitabine bralpamide (fostrox), a pro-drug designed to selectively treat liver cancer and to minimize side effects. Collaborations and partnerships are important parts of Medivir's business model, and the drug development is conducted either by Medivir or in partnership. Birinapant, a SMAC mimetic, is exclusively outlicensed to IGM Biosciences (Nasdaq: IGMS) to be developed in combination with IGM-antibodies for the treatment of solid tumors. Medivir's share (ticker: MVIR) is listed on Nasdaq Stockholm's Small Cap list. www.medivir.com.

1) Rumgay et al.,European Journal of Cancer 2022 vol.161, 108-118.